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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/508,710 | 07/10/2000 | DAVID J. COLE | 33083-PCTUS | 7491 |

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EXAMINER

KRUSE, DAVID H

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1638

DATE MAILED: 10/22/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Applicati n N .

09/508,710

Examiner

David H Kruse

Applicant(s)

COLE ET AL.

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-- The MAILING DATE of this communicati n appears on th c ver sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2002 and 08 July 2002 .
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8-15,23,25-27,29-32,43 and 66-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,8-15,20-23,25-27,29-32,43 and 66-80 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received..
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendments filed 31 May 2002 and 9 July 2002. Applicant indicated in the 9 July 2002 Amendment that it was a further response to their response mailed June 4, 2002, and identified the 9 July 2002 amendment as a Preliminary Amendment. The Examiner, and the Office, has interpreted the 9 July 2002 amendment as a Supplementary Amendment to the Amendment filed 31 May 2002. Applicant is advised to confirm this interpretation in response to this Office action to maintain a clear record in the instant application.
2. Claims 5, 7, 16-19, 34-42, 44, 64 and 65 have been cancelled as requested in the 31 May 2002 Amendment and new claims 66-80 have been added.
3. Claims 21, 31, 32 and 78 have been amended as requested in the 4 June 2002 Amendment.
4. Claims 1-4, 8-15, 23, 25-27, 29-32, 43 and 66-80 are pending in the instant application.
5. The objection to the Title of the Invention is withdrawn in view of Applicant's submission of a more descriptive title in the Amendment filed 31 May 2002.
6. The objection to claims 1, 3 and 4 is withdrawn in view of Applicant's amendments to said claims in the Amendment filed 31 May 2002.
7. The rejection of claims 1-4 under 35 U.S.C. § 101 is withdrawn in view of Applicant's amendments to said claims in the Amendment filed 31 May 2002.

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8. The rejection of claims 1, 4, 8-14, 20, 21, 29 and 30-32 under 35 U.S.C. § 112, second paragraph for indefiniteness for the reasons of record is withdrawn in view of Applicant's amendments to said claims in the Amendment filed 31 May 2002.

9. The rejection of claims 1, 2 and 4 under 35 U.S.C. § 102(a) as being anticipated by Riechers *et al.* 1997 (Plant Physiology 114:1461-1470) is withdrawn in view of Applicant's arguments on pages 13-14 of the Remarks filed 31 May 2002 and the Cummins Declaration filed under 37 C.F.R. § 1.131, on 7 June 2002.

10. The rejection of claim 4 under 35 U.S.C. § 102(e) as being anticipated by McGonigle *et al.* (U.S. Patent 5,962,229, filed 5 September 1997) is withdrawn in view of Applicant's amendment to said claim in the response filed 31 May 2002.

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

12. The abstract of the disclosure submitted 31 May 2002, page 6, does not commence on a separate sheet in accordance with 37 CFR § 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Objections

13. Claims 26 and 27 are objected to because of the following informalities: Claim 13, to which claims 26 and 27 are dependent, is directed to "a plant cell", while claims 26 and 27 recite "plant cells", hence there is a lack of number agreement between the

claims and claim 13. It is recommended that the phrase "plant cells" be amended to read -- the plant cell --. Appropriate correction is required.

14. Claims 3 and 4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

15. Claims 22, 23 and 25 remain rejected and claims 20 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 4 December 2001. Applicant's arguments filed 31 May 2002 have been fully considered but they are not persuasive.

At claims 20-23 and 25, the term "obtaining" or "obtained" renders the claims indefinite because it is unclear what the metes and bounds of "obtaining" or "obtained" are. The word obtain is defined as "To succeed in gaining possession of as the result of planning or endeavor; acquire."¹ In the instant case the claims are directed to a method of -- producing --, "obtaining" does not denote an inventive step in the instant case, but a result of a process of thought. The Examiner notes that Applicant has stated that the indefinite adverb "obtainable" has been amended to use the definite verb

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"obtained", for example in claim 22 (see page 10 of the Remarks, in the Response filed 31 May 2002).

At claim 23, line 3, the phrase "a method" should read -- the method -- in referring to claim 21.

16. Claims 1 and 2 remain rejected and claims 8-15, 20-23, 25-27, 29-32, 43(misidentified as claim 47 in the Office Action mailed 4 December 2001) and 66-80 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 4 December 2001. Applicant's arguments filed 31 May 2002 have been fully considered but they are not persuasive.

Applicant argues that the specification provides a detailed description of selective hybridization and the specification teaches GST sequences with modified nucleotides and/or backbones. In addition, Applicant argues that the specification also teaches ways to identify allelic variants of GST sequences related to SEQ ID NO: 1, the properties of an allelic variant, GST sequences with optimized codon usage and/or engineered restriction sites and how to produce conservative substitutions (see paragraph spanning pages 12-13 of the Remarks filed 31 May 2002). In reference to claims 1 and 2, it remains the Examiner's opinion that Applicant has failed to adequately describe the genus of glutathione S-transferase subunit encoding polynucleotides as broadly claimed. Applicant states on page 16, first paragraph, that the limitation

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“hybridizes selectively” encompasses medium to high stringency, the parenthetical example has not been interpreted by the Examiner to limit said limitation.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Additionally, claims 8-15, 20-23, 25-27, 29-32, 43, 77 and 78 are rejected because said claims are directed to compositions comprising the polynucleotide of claim 1 or to methods of using same, and as such have not been adequately described.

New claims 68-76 and 79-80 are directed to isolated polynucleotides having defined percent identity to SEQ ID NO: 1 or fragments thereof, allelic variations of SEQ ID NO: 1 or to isolated polynucleotides encoding modified variants of SEQ ID NO: 2 at unspecified amino acids. As such it is unclear from the instant specification that Applicant was in possession of said polynucleotides having such varied percent homology to SEQ ID NO: 1 as claimed in claims 68-73, or at claims 74-76 to polynucleotides having 95-99% identity to only fragments of SEQ ID NO: 1, but having other polynucleotide sequences not described herein.

17. Claims 1, 2, 8-15, 20-23, 25-27, 29-32, 43 and 66-80 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1, compositions comprising said polynucleotide and methods of using said polynucleotide, does not reasonably provide enablement for polynucleotides that hybridize to a polynucleotide comprising SEQ ID NO: 1, 70-99% identical thereto or allelic variants, compositions comprising said polynucleotide or method of using said polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are not enabled because they lack an adequate written description as discussed supra. Specifically, one of skill in the art at the time of Applicant's invention would have not known how to make and use the invention as claimed.

Additionally, Applicant has provided limited guidance for the breadth of the instant claims. In particular, at claims 66-76 and 80, said claims are not even limited to polynucleotides encoding a glutathione S-transferase enzyme *per se*. The art teaches that ultimately the function of any DNA sequence, whose identity is based solely on homology, can only be proven by experiments designed to evaluate that function (see Duggleby 1997, Gene 190:245-249, specifically page 248, left column, last paragraph). In addition the art teaches that isolating DNA fragments using stringent hybridization conditions, does not predictably select for DNA fragments whose contiguous nucleotide

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sequence is the same or nearly the same as the probe or sequence of interest.

Fourgoux-Nicol *et al* (1999, Plant Molecular Biology 40:857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65°C (page 859, left column, 2nd paragraph). Fourgoux-Nicol *et al* also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). In the present example, the isolated fragment exhibits less than 50% sequence identity with the probe. Hence, given the limited guidance by Applicant, the state of the art at the time of the invention and the teachings of the art, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to practice the invention as broadly claimed.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1, 2, 8, 9, 66, 67 and 79 are rejected under 35 U.S.C. § 102(b) as being anticipated by Dudler *et al* 1991 (Molecular Plant-Microbe Interactions 4(1): 14-18).

Dudler discloses an isolated polynucleotide encoding a wheat glutathione S-transferase in Figure 1 on page 15 comprising operably linked regulatory sequences that allow expression of the coding sequence in a plant host cell that would hybridize selectively to the coding sequence of SEQ ID NO: 1 or the complement thereof, and is an allelic variant of the polynucleotide shown in SEQ ID NO: 1. Hence, Dudler has previously disclosed all of the claim limitations.

20. Claims 1, 2, 8-15, 20-23, 25-27, 29-32 and 43 remain rejected and claims 66, 67, 74, 77 and 78 are rejected under 35 U.S.C. § 102(e) as being anticipated by McGonigle *et al* (U.S. Patent 5,962,229, filed 5 September 1997). This rejection is repeated for the reason of record as set forth in the last Office action mailed 4 December 2001.

Applicant's arguments filed 31 May 2002 have been fully considered but they are not persuasive.

Applicant argues that the present invention was made prior to August 11, 1997 as evidenced by the Cummins Declaration filed 7 June 2002, and thus the McGonigle '229 patent is not available as 102(e) art (see page 14 of the Remarks filed 31 May 2002). This argument is not found to be persuasive because under the requirements for 102(e), the prior art patent must have been filed prior to Applicant's claimed invention. Since the effective filing date of the instant application is more than 3 months after the effective filing date of the patent, 37 CFR § 1.608(b) requires that applicant must file (1) evidence, such as patents, publications and other documents, and one or more affidavits or declarations which demonstrate that applicant is *prima facie* entitled to a judgment relative to the patentee, and (2) an explanation stating with particularity the

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basis upon which the applicant is *prima facie* entitled to judgment. The patent cannot be overcome by an affidavit or declaration under 37 CFR § 1.131 by only through interference proceedings. See MPEP § 2308.01.

New claims 66, 67, 74, 77 and 78 are also anticipated by McGonigle *et al.* The maize glutathione S-transferase gene of McGonigle would hybridized to the coding sequence of SEQ ID NO: 1 or to its complement under the conditions recited in claims 66 and 67. The Examiner notes that there are no wash limitations in the instant claims that would obviate this rejection. At claim 74, the sequence of McGonigle comprises a 60 contiguous nucleotide sequence at bases 312-384 that is 95% identical to the nucleotide sequence of SEQ ID NO: 1. Claims 77 and 78 are anticipated for the reasons given in the previous Office action mailed 4 December 2001. Hence, all of the claim limitations remain or have been anticipated by McGonigle.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. Claims 1, 2, 8-15, 20-23, 25-27, 29-32, 43, 66, 67, 74, 77, 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGonigle *et al.* (U.S. Patent 5,962,229, filed 5 September 1997) in view of Dudler *et al.* 1991 (Molecular Plant-Microbe Interactions 4(1): 14-18).

The teachings of McGonigle *et al* is outlined supra and in the previous Office action mailed 4 December 2001. Specifically, McGonigle teaches a maize glutathione S-transferase encoding polynucleotide, methods of using said polynucleotide to transform plants and to produce herbicide tolerant transgenic plants useful for controlling weeds at a locus.

McGonigle does not teach an allelic variant of the wheat glutathione S-transferase having the polynucleotide sequence of SEQ ID NO: 1.

Dudler *et al* teaches an allelic variant of the wheat glutathione S-transferase having the polynucleotide sequence of SEQ ID NO: 1 as outlined supra.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of McGonigle to use the polynucleotide of Dudler. Dudler teaches that GSTs have been implicated in the detoxification of herbicides (see page 14, left column, end of paragraph 1, and page 18, left column, first paragraph). Hence, Dudler provides the motivation to use the taught wheat glutathione S-transferase encoding polynucleotide to transform plants and use said transformed plants to control weed at a locus as claimed. One of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of success given the teachings of McGonigle, using the maize GST encoding polynucleotide.

Conclusion

23. Claims 3, 4, 68-73, 75, 76 and 80 are free of the prior art because the prior art neither teaches nor suggests an isolated polynucleotide comprising SEQ ID NO: 1 or encoding SEQ ID NO: 2.

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24. Claims 1, 2, 8-15, 20-23, 25-27, 29-32, 43 and 66-80 are rejected.
25. This Office action is non-final.
26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

David H. Kruse, Ph.D.
15 October 2002